

REMARKS

Entry of the amendment is respectfully requested since it would reduce the issues on appeal, introduces no new matter and is responsive to the Examiner's suggestions given at the interview held on December 20, 2007. Reconsideration in light of the foregoing amendments and remarks that follow is also respectfully requested.

Upon entry of the amendment, claims 1-4, 10, 16, 17, 21 and 23 are pending. Claims 7-9, 11, 18 and 19, withdrawn from consideration by the Examiner pursuant 37 CFR 1.142(b), have been cancelled. Claim 1 has been amend to adopt the Examiner's suggestions (The Examiner indicated that the identification of the active ingredient in claim 1 was not required.), improve readability and address points raised by the Examiner during the interview held on December 20, 2007. Newly added claim 23 is directed to the active ingredients identified in claim 1 prior to the instant amendment. The substance of the interview is accurately set forth on the Interview Summary Form, given to the undersigned at the conclusion of the interview.

Relative to the Examiner's request at the interview, Compound K-76COOH is identified in the speciation on page 23 as being described in U. S. Patent No. 5,506,247 (" '247 patent"). See page 23 of the specification. It appears from the patent that Compound K-76COOH, a monocarboxylic acid derivative of K-76, is recognized in the art. Note "Other References" section. Further, '247 patent indicates that K-76COOH is an oxidation product (silver oxide) of 6,7-diformyl-3', 4', 4a', 5', 6', 7', 8', 8a'-octahydro-4, 6',7'-trihydroxy- 2', 5', 5', 8a'-tetramethyl spiro [(1'(2'H)-naphthalene-2(3H)-benzofuran]. See "2.4 Spirobenzofuran-2(3H)-Cycloalkanes and K-76" section.

The withdrawal of the rejections of the claims based on Lodge (5,462,726), alone or in combination with other references, is noted with appreciation as is the withdrawal of the rejection of the under 35 U.S.C. 112, second paragraph.

Claims 1-4, 10, 16, 17, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of complement activation by sCR1, does not provide enablement for several inhibitors recited in the claims. Applicants respectfully traverse.

The claims have been further limited in light of the Examiner's helpful comments provided at the interview held on the twentieth of December. As amended, the claims recite known complement activation inhibitors and are limited to hypersensitivity treatment where the

hypersensitivity is due to specific amphiphilic carriers- polyethoxylated oil and the complement cascade.

The practice of the invention merely requires the selection of a known “complement activation inhibitor”. There is sufficient guidance provided within the specification, e.g. Example 5, to permit practice of the invention as claimed with the exercise of mere routine experimentation. The examples show successful operation of the invention and provided additional details to aid the artisan of ordinary skill in the practice of the claimed invention.

Accordingly, in light of the amendments to claim 1 and the remarks above, withdrawal of the rejection is respectfully requested.

Claims 1-4, 6, 10, 16-17 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terwogt (Cancer Treatment Reviews, March 1997) or O'Brien (Annals of Oncology, 1992) in view of Ko (5,851,528) and applicant's statements of prior art. Applicants respectfully traverse.

The claims have been amended to clearly indicate that the immediate hypersensitivity reaction treated in the claims is due to the complement cascade, which as explained during the interview is distinct from an allergy reaction, which typically involves IgE.

The teachings of both Terwogt and O'Brien as characterized by the Examiner are noted. It is agreed that neither reference mentions complement activation inhibitors or their use. There is also no suggestion of a relationship between complement system inhibition and the alleviation of the symptoms associated with immediate hypersensitivity due to the complement cascade.

The Examiner's reliance Ko appears to be misplaced, especially as to the claims as amended. Ko makes no mention of complement activation inhibitors. Ko appears interested in treating allergy based reactions. (The claims as amended are limited to treatment of immediate hypersensitivity due to the complement cascade and to the named complement activation inhibitors.) Ko's teachings in this regard appear to be incomplete. Ko does not mention Cremophors. Ko does not mention the treatment of the immediate hypersensitivity caused by Cremophors. Ko does not mention the claimed complement activation inhibitors. Ko does not convey a reasonable expectation that the use of complement activation inhibitors, generally, would alleviate immediate hypersensitivity symptoms caused by the activation of the complement cascade.

Ko teaches specific hybrid peptides and demonstrates their activity in a situation involving an allergic reaction. There is no showing that deals with immediate hypersensitivity due to complement activation.

Further, the unexpected nature of Applicants' discovery should be appreciated from a "fair" reading of the instant specification, which suggests that at the time the application was filed there was a high degree of uncertainty and unpredictability in this technical area, especially, in terms of the cause of the hypersensitivity by Cremophors and paclitaxel and also as to the suitability of claimed complement activation inhibitors to alleviate Cremophor induced hypersensitivity symptoms.

It is respectfully submitted that a proper *prima facie* case of obviousness has not been established. Withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, the application is believed to be in condition for allowance and a notice to that effect is respectfully requested.

Should the Examiner not agree that the Application to be in allowable condition or believe that a conference would be of value in expediting the prosecution of the Application, Applicants request that the Examiner telephone undersigned Counsel to discuss the case and afford Applicants an opportunity to submit any Supplemental Amendment that might advance prosecution and place the Application in allowable condition.

Respectfully submitted,



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